

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment is respectfully requested. Reconsideration of this Application and entry of this Amendment is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

No new matter has been added as a result of the present amendments.

#### **In the Claims**

Claim 1 has been amended to define the layers as polymer layers. Further, claim 1 has been amended to recite "wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight." Support for these amendments can be found in, for example, claims 4 and 5 as originally filed.

Claims 6 and 7 have been amended to now properly depend from claim 1 and claim 7 has been further amended to define the polymer as being part of the polymer layers defined in claim 1.

Claim 11 has been amended to define a "gradient polymer layer." Support for this amendment can be found, for example, in paragraph [0011].

Claim 12 has been amended to define the layers as polymer layers. Further, claim 12 has been amended to recite "wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight." Support for these amendments can be found in, for example, claims 4, 5 and 17 as originally filed.

Claims 18, 20 and 23 have been amended to depend from claim 12 instead of canceled claim 12.

Claims 4, 5 and 17 have been canceled.

#### **35 U.S.C. §112**

Claims 17-25 are rejected under 35 USC §112 as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Office suggests that claims 17 and 19 recite the limitations "said at least one polymer layer" in claim 17 and "said polymer layers in claim 19, and that there is insufficient antecedent basis for these limitations in base claim 12.

Claim 17 has been canceled, mooted the rejection thereof. Claim 12, from which claim 19 depends, has been amended to include “polymer layer” thereby providing antecedent basis for the use of “polymer layers” in claim 19. Claims 18, 20, and 23 have been amended to depend from claim 12 and therefore incorporate the antecedent basis for “polymer layers” therefrom, and the remaining claims 21-22 and 24-25 also incorporate the corrected antecedent basis provided by claims 12. As such, the Applicants request the Office withdraw the 35 USC §112 rejection of claims 17-25.

**35 U.S.C. § 102(b)**

Claims 1-5, 7-13, 15-17 and 19-25 are rejected under 35 USC § 102(b) as being anticipated by Schwarz et al. (US 6,368,658, hereinafter “Schwarz”). The Office asserts that “Schwarz discloses methods and apparatuses for the controlled delivery of at least one pharmaceutical compound, comprising an implantable medical device having a surface and a coating with at least two layers...where one coating incorporates at least a releasable pharmaceutical compound...with another layer having a property affecting the reliability (sic) of the compound and where the layer differs from the first layer.” The Office further asserts that “Schwarz discloses a variety of polymers of different molecular weights being displaced (sic) on the device and further discloses a number of different degradation profiles based on the type of polymer applied...” The Applicants respectfully disagree.

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987). A claimed invention is anticipated only when it is “known to the art in the detail of the claim.” *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be “arranged as in the claim.” *Id.*

The Applicants assert that Schwarz does not expressly or inherently describe each and every element of the presently amended claims. The presently amended claims recite, in part, “polymer layers having at least one physical property affecting the releasability of said releasable pharmaceutical compound that differs from said at least one other layer, wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight.”

In contrast, Schwartz teaches stents with one or more different layers. For example, Schwartz describes a drug polymer layer with a barrier layer applied thereon (column 14, Example 4). The barrier layer is a completely different polymer. Further, in Example 4, Schwartz also teaches that “[t]he release profile of the drug may also be altered by concurrently applying several layers of gradient concentrations to yield a multi-phasic release profile” (column 14, lines 41-44). As such, Schwartz is describing a gradient polymer system with layers differing in polymer concentration, not polymer molecular weight. Schwartz makes no mention of a polymer system for controllable delivery of a pharmaceutical agent by varying the polymer molecular weight between coatings.

Therefore, Schwartz does not expressly or inherently describe each and every element of the presently amended claims and the Applicants request the Office withdraw the 35 USC § 102(b) rejection of claims 1-5, 7-13, 15-17 and 19-25.

### **35 U.S.C. §103 Rejection**

#### **Claims 6 and 18**

Claims 6 and 18 have been rejected under 35 USC §103(a) as being obvious over Schwartz. The Office asserts that it would have been obvious to one of ordinary skill in the art to consider implementing polymer coatings having molecular weights in the range of 1 kDa to 100,000 kDa. The Applicants respectfully disagree.

To reject a claim under 35 U.S.C. §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. *In re Bell*, 26 USPQ.2d 1529 (Fed. Cir. 1992). The Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. *In re Oetiker*, 24 USPQ.2d 1443 (Fed Cir. 1992).

As discussed *supra*, the presently amended claims recite, in part, “polymer layers having at least one physical property affecting the releasability of said releasable pharmaceutical compound that differs from said at least one other layer, wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight.”

In contrast, Schwartz teaches stents with one or more different layers. For example,

Schwartz describes a drug polymer layer with a barrier layer applied thereon (column 14, Example 4). The barrier layer is a different polymer completely. Further, in Example 4, Schwartz also teaches that “[t]he release profile of the drug may also be altered by concurrently applying several layers of gradient concentrations to yield a multi-phasic release profile” (column 14, lines 41-44). As such, Schwartz is describing a gradient polymer system with layers differing in polymer concentration, not polymer molecular weight. Schwartz makes no mention of a polymer system for controllable delivery of a pharmaceutical agent by varying the polymer molecular weight between coatings. Therefore, the Office’s assertion that molecular weights are obvious to those having skill in the art is moot in light of the presently amended claims and the Applicants’ assertions explained *supra*.

As such, Schwartz does not teach or suggest each and every limitation of the presently amended claims, and as a result, the Applicants request the Office withdraw the 35 USC §103(a) rejection of claims 6 and 18.

#### Claim 14

Claim 14 has been rejected under 35 USC §103(a) as being obvious over Schwartz in view of Sirhan et al. (US 6,858,221, hereinafter “Sirhan”). Schwartz does not disclose stents that are self-expanding. As such, the Office combines the teachings of Schwartz with that of Sirhan, who teaches self-expanding stents. The Office asserts that it would have been obvious to one skilled in the art to use a self-expanding stent as a substitution for other kinds of stents. The Applicants respectfully disagree.

As discussed *supra*, the presently amended claims recite, in part, “polymer layers having at least one physical property affecting the releasability of said releasable pharmaceutical compound that differs from said at least one other layer, wherein said at least one physical property affecting the releasability of said at least one pharmaceutical compound is molecular weight.”

In contrast, Schwartz teaches stents with more than one different layer as described *supra*. As such, Schwartz is describing a gradient polymer system with layers differing in polymer concentration, not polymer molecular weight. Schwartz makes no mention of a polymer system for controllable delivery of a pharmaceutical agent by varying the polymer molecular weight between coatings.

The Office attempts to combine the teachings of Schwartz with the teachings of

Sirhan. Sirhan makes no mention of a polymer system for controllable delivery of a pharmaceutical agent by varying the polymer molecular weight between coatings, rather Sirhan simply discloses self-expanding stents (see entire document). The fact that the stent can be self-expanding is moot in light of the fact the combination of references does not teach the polymer systems as presently claimed.

As such, the combination of Schwartz and Sirhan does not teach or suggest each and every limitation of the presently amended claims. Therefore, the Applicants request the Office withdraw the 35 USC §103(a) rejection of claim 14.

### **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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